DETAILED ACTION

Status of the Claims

Claims 1-29 are pending. Claims 1-14 and 16-18 are the subject of this Office Action. Claims 15 and 19-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent Application No. 10/894,400. The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

Claims 1-14 and 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-23 of U.S. Patent Application No. 10/632,008. The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

Claims 1-14 and 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent Application No. 10/409,358. The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

In response the above rejections, Applicants, in their remarks of 14 December 2007 declined to discuss the merits but rather, have opted to address these provisional rejections at a future time when these rejections only remain. Until such time, the rejections are considered proper and maintained.

Claim Rejections – 35 U.S.C. §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-9 are rejected under 35 U.S.C. §102(b) as being anticipated clearly by U.S. Patent No. 5,674,242 [hereinafter referred to as "Phan et al"]. The rejection as set forth in this Office's Action on 14 June 2007 is incorporated herein by reference in its entirety.

In response, Applicants have amended claim 1 to incorporate the limitation "by causing a decrease in a weight-average or number-average molecular weight of the polymer" and argue that: (1) their claims directed to the above new limitation rather than to cross-linking by exposure to UV light (Page 9, Para. 2 of Applicants' Remarks) and the same is not taught by Phan et al; (2) there is no teaching or suggestion in Phan et al of polymers in which radiation is used to increase release of a therapeutic agent from a polymer (Page 9, Para. 4 of Applicants' Remarks); and (3) inherency cannot flow as a necessary conclusion of the teachings of Phan but rather, Phan et al teaches away from the inherency required to support a rejection of the stated claims as anticipated (Page 10, Para. 3 of Applicants' Remarks).

Importantly, the language "a decrease in a weight-average or number-average molecular weight of the polymer," while mechanistic in nature, does not assign to claim 1 patentable weight, because the added language merely describes a potential function of using the device in the manner previously claimed. Despite the amendment, the same therapeutic agent comprising

the same polymeric release region is used in the same host, subject to a radiation dose that gives the same effect to the same patient population. By Applicants' own account,

> "when polymers are exposed to radiation, at least two ***reactions are believed*** to occur" and "[c]rosslinking ***generally*** results in …[and c]hain scission, on the other hand ***generally results*** in ...While polymers ***may display*** both types of reactions, one type of reaction will ***typically*** dominate. For increased release, ***it is preferred to use polymers*** in which chain scission reactions dominate." (Emphasis added).

If, for the sake of *arguendo*, Applicants' position that the added clause gives patentable weight to claim 1 were true, even still, the specification is permissive, but not dispositive of the same being possible as a result of cross-linking. By Applicants' own admission, therefore, it is chain scission that generally, but not always results in reduction in the molecular weight of a polymer. This generalization is not dispositive of crosslinking bringing about a similar result. Thus, Phan et al does not, as claimed, teach away from the inherency required to support the anticipation rejection.

In light of the foregoing, Claims 1 and 4-9 are clearly anticipated by Phan et al.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being obvious over Phan et al in view of U.S. Patent Publication 2002/0107330 A1 [hereinafter referred to as "Pinchuk et

al"](please refer to Pinchuk et al in its entirety) and in further view of U.S. Patent Publication No. 2002/0099438 A1 [hereinafter referred to as "Furst"].

The teachings of Phan et al and related arguments, *supra*, and as well, the teachings of Phan et al and Pinchuk et al from this Office's Action of 14 June 2007 are incorporated herein by reference in their entirety. Applicants' lone argument is that this rejection fails for the reasons set forth in response to this Office's 102(b) reference, as stated *supra*, noting the alleged irrelevance of Phan et al to the instant claims. For the reasons set forth above, Phan et al is deemed relevant and extended to this rejection.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to develop a stent comprising a triblock copolymer such as polystyrene-polyisobutylene-polystyrene which comprises a plurality of $-CH_2-CR_1R_2$ groups and houses a therapeutic agent for release.

Claims 2-3 are rejected under 35 U.S.C. 103(a) as being obvious over Phan et al in view of U.S. Patent Publication No. 6,537,569 [hereinafter referred to as "Cruise"](please refer to Cruise in its entirety).

The teachings of Phan et al and related arguments, *supra*, and as well, the teachings of Phan et al and Cruise et al from this Office's Action of 14 June 2007 are incorporated herein by reference in their entirety. Applicants' lone argument is that this rejection fails for the reasons set forth in response to this Office's 102(b) reference, as stated *supra*, noting the alleged irrelevance of Phan et al to the instant claims. For the reasons set forth above, Phan et al is deemed relevant and extended to this rejection.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to develop a stent with a polymeric release region and therapeutic agent wherein the polymeric release region would be treated with a radiation dose in excess of 10,000,000 rads to increase the cumulative release of the therapeutic agents therein.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614